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10/666,562

09/17/2003

Ned S. Rasor

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EXAMINER

SU, SUSAN SHAN

ART UNIT

PAPER NUMBER

4193

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/666,562 | <b>Applicant(s)</b><br>RASOR ET AL. |  |
|                              | <b>Examiner</b><br>SUSAN SU          | <b>Art Unit</b><br>4193             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>23 March 2007 &amp; 11 April 2006</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Priority***

1. Applicant's claim to priority of parent application 09/795,648 now Patent 6,652,479, filed February 28, 2001, which claims benefit of provisional application 60/185,495 filed February 28, 2000, is recognized.

### ***Claim Objections***

2. Claim 6 is objected to because of the following informalities: lack of antecedent basis for "the container." The examiner believes that the instant claim is dependent on Claim 3 instead of Claim 1, hence suggests that "method of Claim 1" be changed to --method of Claim 3-- and examines the instant claim based on the assumption that it is dependent on Claim 3. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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5. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being obvious over Maraco, Jr. (U.S. Patent 5,848,998) in view of Carter et al. (U.S. Patent 5,288,462).

With regard to Claim 1, Maraco, Jr. (hereinafter Maraco) teaches a method (inherent in the use of the apparatus) for transcutaneous delivery of carbon dioxide to an individual comprising the steps of selecting a portion of the individual's skin (as shown by the Figs. 1 & 2 showing a container 12 covering various parts of the patient's body); and applying a quantity of fluid to the selected portion of the individual's skin (Col. 2 lines 55-57). However, Maraco does not teach that the fluid is carbonated water. Carter et al. (hereinafter Carter) teaches using carbonated water to sterilize medical tools (Col. 2 lines 26-34). It is held by the examiner that since the use of carbon dioxide gas in sterilizing anything from wounds and medical tools to foods and liquids, it takes only common sense and routine skill for one of ordinary skill in the art to apply the use of carbonated water to the treatment of body ailments. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Maraco with Carter for the purpose of effectively treating the ailments of a patient without the danger of a highly pressurized carbon dioxide tank (fissure in a tank of carbonated water would cause leaks rather than explosions).

With regard to Claim 2, as applied to Claim 1 above, Maraco and Carter combine to teach the limitations of this claim except submerging the selected portion of the individual's skin in the carbonated water. However, it is held by the examiner that it is common practice to submerge an individual's skin for treating ailments (such as in spas and for treating burn victims). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Maraco and Carter for the purpose of ensuring a constant contact between the carbonated water and the individual's skin.

With regard to Claim 3, as applied to Claim 1, Maraco also teaches the steps of placing a selected quantity of the carbonated water in a container (88, Fig. 4) that defines an opening

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(90), said opening adapted to be sealed against the selected portion of the individual's skin; and placing the opening over the selected portion of the individual's skin and orienting the container such that the carbonated water contacts the selected portion of the individual's skin (see figure).

With regard to Claims 4 & 5, as applied to Claims 2 & 3 above, Maraco and Carter combine to teach the limitations of this claim except that the selected portion of the individual's skin is submerged in carbonated water for at least three minutes. However, it is asserted by the examiner that the time for skin to be submerged in a liquid for therapeutic or treatment purposes is determined by the strength of the active ingredient (in this case carbon dioxide in the water) and each individual's unique response to the treatment plan. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the above combination without undue experimentation so that the skin is submerged for at least 3 minutes so that a beneficial effect can be felt by the individual undergoing the treatment.

With regard to Claims 6 & 7, as applied to Claim 3, Maraco also teaches that the container (88) is large enough to receive substantially all of the individual's body (see Fig. 4), and wherein the selected portion of the individual's skin comprises substantially all of the individual's transcutaneous skin surface (the selected portion is determined by the extent of the containment of the container); and the applying step further comprises submerging the selected portion of the individual's skin in the carbonated water (already explained in Claim 3). The limitation in Claim 7 is discussed in Claim 4 above.

With regard to Claim 8, as applied to Claim 1 above, Maraco and Carter teach the limitations of this claim except selecting a portion of skin adjacent to an area of the individual's body that is experiencing pain. However, Maraco teaches that the treatment is applied to wound sites (Col. 2 lines 41-43), and it is common knowledge that wounds are generally painful. Therefore it would have been obvious to one of ordinary skill in the art at the time of the

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invention to modify Maraco and Carter for the purpose of applying the treatment to the appropriate location.

6. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being obvious over Maraco in view of Carter further in view of Aggarwal et al. (WO 95/23596).

7. As applied to Claim 1 above, Maraco and Carter teaches the limitations of this claim except placing a selected quantity of carbonated water in an absorbent material or placing the absorbent material against the selected portion of the individual's skin. Aggarwal et al. (hereinafter Aggarwal teaches placing a selected quantity of therapeutic solution in an absorbent material (pg. 2 lines 5-10), and placing the absorbent material against the selected portion of the individual's skin (pg. 2 lines 11-14, 18-20). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Maraco and Carter with Aggarwal for the purpose of having a portable and disposable means for applying the treatment to the selected area of the skin. The limitation of Claim 10 is discussed in Claim 4 above.

8. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being obvious over Maraco in view of Carter further in view of Cohen (U.S. Patent 4,175,704).

With regard to Claim 11, as applied to Claim 1, Maraco and Carter teach the limitations of this claim except that the portion of the individual's skin further comprises a mucous membrane. Cohen teaches applying a solution to a portion of an individual's skin that comprises a mucous membrane (inherent in the use of the device as a nose spray, Col. 3 lines 34-35). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Maraco and Carter with Cohen for the purpose of treating an area of the body where the skin is sensitive.

With regard to Claims 12 & 13, as applied to Claims 8 & 11 above, Maraco and Carter combine to teach the limitations of this claim except placing carbonated water into a container from which a spray of carbonated water may be generated or spraying a quantity of carbonated

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water on the selected portion of the individual's skin. Cohen teaches placing a therapeutic solution (10) into a container (12 and 30 combined) from which a spray of the solution may be generated (see Fig. 6) and spraying a quantity of the solution on the selected portion of the individual's skin (inherent in the use of the device as a nose spray, Col. 3 lines 34-35). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Maraco and Carter with Cohen for the purpose of having a portable treatment for an area of the body with sensitive skin.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Sims (U.S. PGPub 2006/0251542) teaches a method to sterilize medical instruments using carbonated water.

Swenson et al. (U.S. Patent 6,113,922) teaches a composition that comprises carbon dioxide and is externally used for the treatment of wounds.

Rosati (U.S. PGPub 204/026253) teaches a dressing for supplying a gas such as carbon dioxide to the wound for treatment purposes.

Thrash et al. (U.S. Patent 6,638,236) teaches a sealed irrigation system that applies treatment fluid to a selected external skin of the individual.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 8:30AM-6:00PM EST (alternate Fridays off).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Taghi Arani can be reached on 571-272-3787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. S./  
Examiner, Art Unit 4193

/Taghi T. Arani/  
Supervisory Patent Examiner, Art Unit 4193  
4/26/2008